

UNCLAS SECTION 01 OF 07 GENEVA 000837

SIPDIS

PASS USTR FOR MENDENHALL, ESPINEL, PECK  
STATE FOR WILSON, FELT  
USDA FOR FAS/ITP/SCHWARTZ, TTB/TOBIASSE  
USPTO FOR LASHLEY, SALMON  
USDOC FOR ITA/SCHLEGELMILCH

E.O. 12958: N/A

TAGS: [EAGR](#) [ETRD](#) [WTRO](#)

SUBJECT: WTO TRIPS COUNCIL, MARCH 8-9, 2005

11. SUMMARY: The TRIPS Council meeting took place on Wednesday and Thursday, March 8-9, 2005. Mr. Tony Miller of Hong Kong, China chaired the meeting. There was an informal session held on the morning of March 8, with the formal session beginning on the afternoon of the first and continuing to the next day. Most discussion took place with regard to two agenda items. With respect to the Decision on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, the African Group tabled a paper clarifying some of their reasons for their proposal from the previous meeting and the United States tabled a paper clarifying views on the amendment process. As to the relationship of TRIPS and the CBD, new documents were tabled by Peru and the delegations of Brazil, India and a number of co-sponsors. END OF SUMMARY

12. INFORMAL SESSION

13. The TRIPS Council met in informal session on the morning of December 1. The Chair raised three issues for discussion: (1) the decision on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, (2) structure of discussions under the agenda items relating to Article 27(3)(b), the relationship of TRIPS and CBD and protection of traditional knowledge (TK) and folklore, and (3) implementation issues.

14. The Nigerian delegation made a brief statement under item one that its delegation would make a submission at the formal session. The Chair then asked whether any delegation had (1) any additional flexibility on the matter in order to meet the deadline, and (2) if meeting the deadline was not possible, any ideas on further work. No delegation took the floor.

15. On the second item, the Chair noted that he had undertaken consultations on this issue and noted widespread view that current discussions were fruitful and allowing all views. He would present no new proposal on how to pursue work and suggested that we take up the three agenda items together, as in past meetings, based on the contribution of Members. No delegation commented on this issue.

16. On implementation, the Chair noted that a progress report would be prepared and recalled the five options: (1) resolve issue, (2) no further action, (3) refer issue to a negotiating body, (4) work under subsidiary body under the TNC, (5) undertake further work at the TNC. The Chair noted that his consultations included a wide variety of responses. For example, some delegations wanted issues to move to a negotiating body, others saw that the Ministerial declaration did not include negotiations on these issues and that a negotiating body or the TNC would not be acceptable. He noted some delegations identified tirets 88 and 95, both relating to the relationship of the TRIPS Agreement and the Convention on Biological Diversity (CBD), as priorities.

17. India gave a statement noting the importance of issues relating to the relationship of the TRIPS Agreement and the CBD. The Indian delegation asked the Chair to conduct dedicated consultations on the issue in his role as Friend of the DG. Brazil quickly supported the suggestion for consultations. The delegations of Ecuador, Peru, Thailand, Dominican Republic, Turkey, Bolivia all supported the request for consultations. Japan initially objected to the consultations citing potential duplication of work and noting WIPO as the appropriate forum for discussion of these issues. The US noted that we were satisfied with the work of TRIPS Council on these issues, but we did not object to consultations.

18. In response, the Chair asked whether delegations were ready to hold such consultations at that moment. India and Brazil took the floor to welcome consultations and noted that the TRIPS Council should focus on finding the contours of a solution in its work, with India in particular stating that a disclosure requirement had overwhelming support and the Council should start work on an amendment of the TRIPS Agreement. Brazil also requested a work program on the issue. Ecuador, Uganda, Malaysia, Peru, Zimbabwe, and India

all took the floor to support new patent disclosure requirements. Uganda cited the need for more input from Africa as this region was a subject for "plunder."

¶19. The US noted its previous paper on the issue, that it did not believe there was a conflict between the TRIPS and the CBD and that it does not support new patent disclosure requirements to resolve this issue. The US noted its proposals for alternative solutions to the widely shared objectives of providing prior informed consent, equitable benefit-sharing from the use of genetic resources and/or traditional knowledge and preventing erroneously granted patents.

¶10. AGENDA

¶11. Many agenda items passed without significant discussion. These items included: notifications under provisions of the TRIPS agreement, review of implementation of the TRIPS Agreement under Article 71.1, review of the provisions of the section on geographical indications under Article 24.2, follow-up to the review under paragraph 2 of the decision on the implementation of TRIPS Article 66.2, technical cooperation and capacity-building, special and differential treatment proposals referred to the council, and observer status of intergovernmental organizations. A read-out of the remaining agenda items follows below.

¶12. REVIEW OF NATIONAL IMPLEMENTING LEGISLATION

¶13. Upon receipt of outstanding answers, the follow-up to the review of Armenia was deleted from the Council's Agenda.

¶14. review of the provisions of Article 27.3(b), the relationship of the TRIPS Agreement and the CBD and the protection of traditional knowledge and folklore

¶15. Peru first made a general statement that TRIPS Council was the proper forum for this topic and that the discussion was sufficiently mature and needed concrete action. Peru wanted a solution by the end of the development round in order to allow developing countries to solve the problems they have. Peru then introduced its document IP/C/W/441, noting that various offices in its government are investigating 50 products of Peruvian to determine whether country of origin receives. They stressed the large number of resources needed to search and analyze patents of major patent offices in the US, Japan and Europe, but they feel the need to do so in order to combat bio-piracy.

¶16. Brazil, on behalf of Brazil, India and a number of co-sponsors, introduced a paper (IP/C/W/442) explaining the proposal for a new patent disclosure requirement to disclose evidence of equitable benefit-sharing under a relevant national regime consistent with an earlier unsuccessful proposal by the co-sponsors to establish a checklist for TRIPS Council work in this area. Then, only as the delegation of Brazil, they expressed sympathy for Peru and noted a number of examples in which others had attempted to take out patent rights on genetic resources and traditional knowledge from the Amazon regions of Brazil, but also someone "stealing" the name of a fruit and using it as a trademark.

¶17. India then intervened to support the introduction of document IP/C/W/442 by Brazil and to emphasize its view that a mandatory international patent disclosure requirement is necessary to achieve our objectives. India then introduced, on behalf of India and Brazil, the paper IP/C/W/443, which provides "technical comments," point-by-point, on the previous submission by the United States (IP/C/W/434). Their general comments were that they agreed with the United States that national laws are essential, but that they are not enough as access and benefit-sharing was only effective if requirements were mandatory and enforceable across borders. While they agreed that patenting, per se, does not constitute misappropriation, they stated that disclosure requirements help identify "opportunity of misappropriation." They believed that this discussion showed that there is no alternative to mandatory patent disclosure requirements to achieve the shared objectives of the TRIPS Council and that action was needed to address the mandate under paragraphs 12 and 19 of the Doha Ministerial Declaration.

¶18. A large number of developing countries, including China, Cuba, Ecuador, Indonesia, Thailand, Kenya expressed support for document IP/C/W/442 and called for a satisfactory solution for the Doha round on these issues.

¶19. New Zealand stated that it saw value in exploring how IP can assist implementation of the CBD, but had no definitive view, although it noted that disclosure, in particular of source and/or country of origin, might support CBD. They stated that, nonetheless, national systems were to play a primary role and the answers to non-compliance

with prior informed consent and benefit-sharing were not in the patent system, which was not the appropriate means to ensure prior informed consent and benefit-sharing. New Zealand noted that only a handful of countries have implemented ABS systems, without which patent disclosure cannot even play a supporting role. New Zealand further stated that Members should be realistic and not overestimate potential "green gold." They further noted that they supported the Canadian proposal to see how systems would work in practice.

120. Australia stated that it saw no conflict between TRIPS and the CBD, and that the role of patent system here is not clear. Australia noted that the possible effects of invalidating patents, including that there would be no way to share benefits. They were also wary of ongoing burdens on patent applications and patent offices.

121. The EC noted their new paper, submitted to the WIPO, which proposes a disclosure requirement for origin, but not for evidence of prior informed consent or benefit-sharing, as these latter two proposals would seriously overburden patent offices. They also noted that certificates of origin may be a good idea, but not at this stage. The EC also did not support any sanctions inside the patent system that, for example, would include revocation of a patent.

122. The United States stated that it sees no conflict between the TRIPS Agreement and the CBD. The US maintained that the most effective means to achieve the objectives of authorized access to genetic resources and the equitable sharing of benefits of such resources is through tailored, national solutions to meet practical concerns and actual needs, while the proposed new patent disclosure requirement will not achieve these important objectives and may have significant negative consequences, such as undermining the economic development incentives that patents provide as well as undermining potential benefit-sharing from patents. On this point, it was noted that the proposed remedy of some, invalidating a patent based on inadequate disclosure, would destroy the benefit sought, rather than ensuring such a benefit accrues to the appropriate party. The US noted growing recognition that new patent disclosure requirements, in and of themselves, will not work to ensure the objectives sought and that there is growing recognition of the necessity of contract-based access and benefit-sharing systems. The US also noted Peru's paper, and noted that the US had reviewed certain patents granted on maca and chancapiedra, mentioned in the paper, that appeared to fulfill patentability criteria and did not represent examples of biopiracy. The US then rebutted arguments that new patent disclosure requirements may be necessary to enforce ABS regimes, noting that such regimes can be adequately enforced by criminal and civil provisions outside the patent system.

123. Turkey noted that this issue was as important as GI extension, they welcomed the EC proposal at WIPO and stated that there is a need for the global problem of bio-piracy. Norway noted that it is reviewing its policy, that it viewed the EC proposal very positively, and continues to consider WIPO very important.

124. Canada associated with the statements of Australia and New Zealand, and stated that there is no conflict between TRIPS and CBD. They remained unconvinced that patent law was the best way to ensure prior informed consent or benefit-sharing. Canada expressed that it was prepared to work with an "open mind" and they thanked Peru and the United States for an exchange based on real-life situations and would invite others to do so.

125. Japan noted that there is no conflict between TRIPS and CBD. As to proposals on patent disclosure, these needed to be viewed from the perspective of the patent system. They noted that disclosure of genetic resources should be discussed at the IGC of WIPO and noted that the DG of WIPO has stated that this should be done in an accelerated manner. Japan stated that it shared the views of the United States to tackle biopiracy in that the US proposal helps to attack biopiracy without burdening the patent system.

126. Peru took the floor again to thank Brazil, India and the EC for their submissions and to have some additional comments to the statement of the US. They noted that the searches they have cited are illustrative of their processes and not evidence of biopiracy, but only where there could be a problem. Peru stressed that they wanted to show that if a disclosure requirement were to be implemented it would be much simpler for developing countries to monitor bio-piracy. Currently, having to search patent databases was time consuming and expensive and all costs were on provider countries.

127. Switzerland supported more discussions with respect to ABS systems currently in force at the national level. They then addressed questions to other delegations. To Brazil,

India and the co-sponsors of their documents, they asked questions regarding definitions of "misappropriation" and "biopiracy" as well as "country of origin." To the United States, they asked about the applicability of the contract-based approach to transboundary cases. They also asked some technical questions to the EC.

¶28. Philippines supported Brazil, India and others and stressed that national benefit-sharing schemes are not seen as proving to be adequate.

¶29. Brazil and India took the floor again at the end of the session to stress points made previously regarding the discussion. In particular Brazil emphasized that it had never suggested that patent disclosure requirements would solve all the problems that developing countries face, but that it can be a contribution. While many countries have not set up ABS systems, yet, all CBD Members were expected to implement prior informed consent and equitable benefit-sharing and these principles must be respected even where regimes have not yet been set up in that country. Brazil then noted other forums, such as WIPO, cited by Members as relevant. Brazil then noted that not only the IGC, but also the PCT as well as the SPLT, where some were trying to undermine flexibilities under TRIPS. India then emphasized a number of general points, including their view that patent disclosure requirements are necessary for an eventual solution. They also rebutted the EC argument that only disclosure of origin is mature, noting that disclosure of evidence of prior informed consent and equitable benefit-sharing is also necessary. They also looked forward to consultations held by the Chair, as Friend of the DG, on this issue.

¶30. Decision on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health

¶31. The Chair opened discussion by noting significant differences among Members that were apparent from the consultations that he had held. Further, he noted new papers from the African Group, the Commonwealth Secretariat, and the United States.

¶32. Nigeria, on behalf of the African Group, introduced the African Group proposal (IP/C/W/440) regarding legal arguments supporting its previous proposal for an amendment to the TRIPS Agreement to implement paragraph 11 of the August 30, 2003 solution (IP/C/W/437). They maintained that their proposal is based, as appropriate, on the Decision as instructed by paragraph 11 and that the proposal eliminates a number of provisions that, in their view, are redundant or where the purpose was served in other parts of the TRIPS Agreement, and believed their approach to be a viable basis for undertaking an amendment. With respect to the Chairman's Statement, Nigeria stated that the purposes of the Statement were already served or are redundant and thereby no longer necessary or that the purposes were already served by other parts of the TRIPS Agreement.

¶33. Nigeria, in lieu of Barbados, also introduced the document regarding the meeting of the Commonwealth Secretariat on implementing the Decision on Paragraph 6 of the Doha Declaration on TRIPS and Public Health. They noted the following points in particular: (1) the quality and safety of medicines produced under compulsory license, (2) concerns regarding Free Trade Agreement provisions regarding undisclosed test data.

¶34. The United States introduced a new paper, IP/C/W/444. The United States noted strong support for the August 20, 2003 solution, stated its support for Members' effective and appropriate use of the solution and remained committed to reaching an expeditious consensus on the amendment process. The US maintained that the amendment must preserve the entire agreement reached in August 30, 2003 and must therefore include an express reference to both the General Council decision and the Chairman's Statement. The US reiterated that it viewed this as a technical exercise that should not reopen substantive issues. The US also noted several concerns regarding the African Group proposal, including that it does not make any reference to the Chairman's Statement and that it omits key safeguards from the decision. The US reiterated that it prefers a footnote approach that reference both the General Council decision text and the Chairman's Statement as an optimum solution but that it is willing to consider any other options for an amendment that includes both the General Council decision text and the Chairman's Statement.

¶35. The EC noted that it was committed to the March 2005 deadline and that it viewed this process as a purely technical exercise without re-opening substance. They stated that it was their impression that some delegations were trying to get now what they were unable to achieve in

August 2003. The EC did not share the African Group view that some provisions are redundant or already covered by the TRIPS Agreement. They then listed changes made in a paragraph-by-paragraph fashion. They also stated that the interpretation of "where appropriate" in the African Group paper was too broad.

¶36. Korea noted the long, difficult negotiations and stated that substance of the August 30, 2003 solution should not be reopened. They noted that some provisions, such as the preamble and paragraph 11 may be OK, it did not believe elimination or modification of other provisions was justified. On the Chairman's Statement, they noted that it was an integral part of the solution and that it contained "key shared understandings" but that the legal status should not be changed including the status of the voluntary opt-outs.

¶37. Canada spoke with reference to the Commonwealth paper and noted that it appeared that the August 30, 2003 decision was already working as evidence confirms that price levels have fallen to as low as one-tenth the price prior to the August solution.

¶38. Jamaica intervened first to note its participation in the Commonwealth session and the emphasis on quality, safety and effectiveness welcoming steps by exporters to ensure that drugs produced under compulsory license meet safety standards of exporting countries. Jamaica then stated that they did not support the footnote approach and did not support including the Chairman's Statement as that had been a confidence building measure that has served its purpose.

¶39. The delegations of Argentina welcomed the African Group Proposal as helping to allow an amendment within the time limits. Brazil suggested that it was a good basis for work, and noted that it reflected the decision to work "where appropriate." India also stated that the African Group proposal was a good basis for further contributions.

¶40. Japan stated that the Council should put what was agreed into a TRIPS amendment not to interpret what was agreed. The footnote is the simplest and surest way. They then stated that the Council should not re-negotiate what was agreed. Japan also noted a number of problems with IP/C/W/437, including that it does not include certain provisions and modifies others and further does not refer to the Chairman's Statement.

¶41. Uganda noted that it considers the August 2003 solution as an important step to ensure access. However, it noted concerns regarding how free trade agreements might prevent a member from taking steps to ensure public health and asked the United States to clarify its statement made at the Commonwealth workshop.

¶42. In response, the United States noted that the provisions of its free trade agreements do not stand in the way of the effective utilization of the August 30, 2003 solution. Indeed, a number of its free trade agreements expressly state that nothing in the intellectual property chapters of those agreements affect the relevant country's ability to take measures necessary to protect public health.

¶43. Israel noted that it accepts the decision and statement together. However, they stated that there should be no changes in incorporation, including the voluntary opt-outs. Chinese Taipei stated that they will not support any suggestion to alter the legal status of opt-outs. Korea, Hong Kong, China and Turkey also stated that the voluntary nature of the opt-outs need to be preserved.

¶44. Switzerland stated that the amendment should be a purely technical amendment that fairly translates what was agreed. They stated the African Group proposal was unacceptable as it would re-open negotiations. They noted that many countries, including Switzerland, were revising their laws to implement the solution. They added that a footnote or an annex could be used without affecting the structure of the TRIPS Agreement, but they are open to other forms of the solution. Switzerland added that the Chairman's Statement was part of the consensus and that, otherwise, Switzerland could not have shared the consensus. There would have been no solution without the Chairman's Statement.

¶45. Kenya began by noting that all Members were committed to the March 2005 deadline. Kenya stated that the decision was very clear that the amendment was to be based "where appropriate" on the Decision and not the Chairman's Statement. They then went through a number of provisions that they felt are not appropriate in the amendment, including the preamble and certain other paragraphs. Further, Kenya stated that a footnote was not the most appropriate way to amend. He also noted that the Chairman's Statement should not be reflected and raised the



issue, in the statement, regarding that the solution should not be for commercial purposes. They asked, if not, how can developing countries build capacity in these areas

¶46. The Philippines added that we should go through the African Group proposal paragraph-by-paragraph. With respect to the Chairman's Statement, the Philippines stated that, at most, this was interpretive context. They stated that the Chairman's statement could be read out again at time of the adoption of the amendment subject to the condition that any Member be able to read out their own statement of interpretation.

¶47. Switzerland noted that a paragraph-by-paragraph approach would open a "pandora's box" and may lead to re-starting negotiations. Instead, the Council should focus on possibilities to integrate the decision as a whole into the TRIPS Agreement. As to the Chairman's Statement, he reiterated that it allowed all Member to join consensus and represented in its own terms "key shared understandings of members." Switzerland then stated that it was essential to incorporate this.

¶48. Malaysia noted differing views on the decision, but cited the African Group paper that it was based "where appropriate" on the decision. Malaysia stated that it was unacceptable to upgrade the status of the Chairman's Statement by incorporating it and that it was also unacceptable to re-read the Chairman's Statement as some have suggested.

¶49. The Chair then noted that, due to the fact that he would be stepping down as Chair at the end of the meeting, he proposed that he would suspend the meeting after this session pending further consultations on this issue to see if progress could be made by the end of March deadline. There was no objection. At the time of this report, the Chair has convened one set of further consultations on which progress did not appear to be made.

¶50. REQUEST FROM MALDIVES FOR AN EXTENSION OF THE TRANSITION PERIOD UNDER ARTICLE 66.1 OF THE TRIPS AGREEMENT

¶51. The Chair noted that, in light of the tsunami in the region, the Maldives may withdraw its graduate status under the UN system. The decision to graduate Maldives, in any event, is not immediately effective and Maldives would retain its least developed country status until December 2005. There would be no TRIPS Council issue until 2006. In this light, the Chair suggested the TRIPS Council take up the matter later this issue, and that consultations be coordinated between the TRIPS Council Chair and the Chair of the Committee on Trade and Development (CTD).

¶52. NON-VIOLATION AND SITUATION COMPLAINTS

¶53. Korea began by noting that it shares the view of the vast majority that non-violation, nullification and impairment (NVNI) complaints were designed primarily for market access and would introduce uncertainties into the TRIPS Agreement. Peru restated that it does not believe that NVNI is appropriate in TRIPS and that it thought the issue should be wrapped up in the Hong Kong ministerial at the end of 2005. For various reasons, Ecuador, the EC, the Philippines, Canada, Brazil, India, Malaysia, and Argentina all spoke to oppose the application of these complaints in TRIPS.

¶54. The United States noted the US continued to consider that NVNI complaints are fully appropriate in the TRIPS context and expect the moratorium to expire at the Sixth Ministerial conference.

¶55. Japan supported continued discussion of the scope and modalities and such complaints in the TRIPS context.

¶56. INFORMATION ON RELEVANT DEVELOPMENTS ELSEWHERE IN THE WTO

¶57. The EC raised the issue of lack of compliance by the United States with the WTO panel decision on the Section 110(5) dispute under TRIPS Article 68. They asked three questions: (1) Are there any specific legislative initiatives in the US to bring the Copyright Act into compliance with TRIPS? In other words, during the past 4 years, has the US Congress discussed any piece of legislation amending Section 110(5) of the Copyright Act? (2) What specific steps is the US Administration taking to ensure that the US brings its Copyright Act into conformity with the TRIPS Agreement? Has there been any written communication to Congress that the US could share? (3) When does the US consider that it will finalize its work to comply with the WTO ruling, which was adopted in July 2000?

¶58. The United States took the floor to respond that the U.S. Administration has been consulting on this matter

with the U.S. Congress, and we will continue to work with the Congress and confer with the European Communities in order to reach a mutually satisfactory resolution of this matter, although it noted that the Dispute Settlement Body was, in its view, the more appropriate forum for a discussion of disputes, including compliance issues related to those disputes.

¶59. OTHER BUSINESS

¶60. The EC raised the issue of enforcement and requested that this item be added permanently to the agenda of the TRIPS Council. They noted global problems of counterfeit goods that threaten legitimate industries.

¶61. Brazil, Argentina, India, and the Philippines noted that they did not have advance notice of this issue and did not wish to agree to a permanent additional agenda item at this time.

¶62. The Chair, noted that as long as Rules 3, 4 and 6 of the General Council Rules of Procedure are followed, any item can appear on the agenda. The Chair also noted that it was not WTO practice to bar discussion of an item unless it is outside the terms of reference of that body.

¶63. ELECTION OF CHAIRPERSON

¶64. The TRIPS Council unanimously elected Ambassador Choi of the Republic of Korea as the next TRIPS Council Chair.

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